K05 c702

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510(k) Summary

March 16th 2005

1 Submitter

NeuroSystems LLC
103 Pomfret Road
Woodstock
Vermont 05091-8029
USA

Contact Person: Dr James R Petite Jr
Telephone: (802) 457 9866
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2 Name of Device

Proprietary Name: NeuroSystems 1™ Monitor

Common Name: Multimodality Neurosurgical ICU monitor

Device Classification: Intracranial pressure monitoring devices have been placed in Class II as per 21 CFR Regulation Number 882.1620 and assigned the Product Code GWM.

3 Predicate Devices

The components of the NeuroSystems 1™ system are substantially equivalent to the following legally marketed devices:

K013930 Novus Monitoring Limited NeuroSensor® System

K980380 Diametrics Medical Limited Neurotrend System

This statement is based on the subject device's similarity to the predicate devices in intended use, design and principles of operation.

4 Device Description

The NeuroSystems 1™ monitor is a secondary display system that collects together on a single large color display screen all of the measured variables relevant to the multi-modality monitoring of the patient in a neurosurgical intensive care unit. The NeuroSystems 1™ monitor has inputs to receive analog data from primary monitors used in the measurement of intracranial pressure, cerebral blood flow, brain tissue oxygen, brain temperature and pH, carbon dioxide and arterial blood pressure. The monitor can also derive the cerebral perfusion pressure.

The NeuroSystems 1™ monitor displays the measured and derived variables in digital and analog trace form, and can store and display trends over periods of 1,2,8 or 24 hours. The system also facilitates the display of the interrelationships between the measured and derived variables. This allows the approximation of Cerebral Autoregulation, Vasoreactivity and O_2 Metabolic Index.

5 Intended Use

The NeuroSystems 1™ monitor has been designed for use by a qualified neurosurgeon to display variables from existing legally marketed primary measuring devices used to monitor neurosurgical patients. The variables displayed by the NeuroSystems 1™ monitor include intracranial pressure, cerebral blood flow, brain tissue oxygen, brain temperature and pH, carbon dioxide and arterial blood pressure, and these are presented both continuously and as trends in these variables, and in the form of relationship graphs. The presentation of both measured variables and the relationships between them is intended as an adjunct to the information provided by existing primary monitors, and the NeuroSystems 1™ monitor should not be used alone as the sole basis for decisions as to diagnosis or therapy.

6 Summary of Substantial Equivalence

The NeuroSystems 1™ system is similar in design, intended use and performance characteristics to the predicate devices. It differs in requiring legally marketed primary monitors to be the interface between the secondary monitor and the patient connected sensors, and in providing the display of measured variables, derived variables and data relationships on a secondary monitor. No new issues of safety or effectiveness are introduced by using this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 17 2005

Dr. James R. Petite Jr.
President
NeuroSystems LLC
103 Pomfret Road
Woodstock, Vermont 05091-8029

Re: K050702
Trade/Device Name: NeuroSystems 1™ Monitor
Regulation Number: 21 CFR 882.1620
Regulation Name: Intracranial pressure monitoring device
Regulatory Class: II
Product Code: GWM
Dated: March 16, 2005
Received: March 18, 2005

Dear Dr. Petite:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if Known): K050702

Device Name: NeuroSystems 1™ Monitor

Indications for Use: The NeuroSystems 1™ monitor has been designed for use by a qualified neurosurgeon to display variables from existing legally marketed primary measuring devices used to monitor neurosurgical patients. The variables displayed by the NeuroSystems 1™ monitor include intracranial pressure, cerebral blood flow, brain tissue oxygen, brain temperature and pH, carbon dioxide and arterial blood pressure, and these are presented both continuously and as trends in these variables, and in the form of relationship graphs. The presentation of both measured variables and the relationships between them is intended as an adjunct to the information provided by existing primary monitors, and the NeuroSystems 1™ monitor should not be used alone as the sole basis for decisions as to diagnosis or therapy.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFGR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K050702